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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------|
| 09/838,618 | 04/19/2001 | Brett T. Haarala | 10123/01101 | 3578 |
| 7590 | 03/09/2004 | | | EXAMINER |
| Fay Kaplun & Marcin, LLP 150 Broadway Suite 702 New York, NY 10038 | | | BUECHNER, PATRICK M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3754 | |
| | | | DATE MAILED: 03/09/2004 20 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/838,618 | HAARALA ET AL. |
| | Examiner | Art Unit |
| | Patrick M Buechner | 3754 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-60 is/are pending in the application.
 - 4a) Of the above claim(s) 1-42 and 47-60 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 43-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Response to Arguments

1. In view of the appeal brief filed on 2/9/2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US 5,3797,888).

Yoon discloses a medical device (20) having an elongate catheter (22) with an external surface and an internal surface defining an internal lumen (Figure 3) and having a compound slit

located at a generally hemispherical distal end portion of the catheter and extending from the external surface to the internal surface (unlabelled Figure 2).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon in view of Phelps et al. (US 6,419,659).

Yoon discloses all the limitations of claim 45, as discussed above in 3, with the exception of a collar disposed adjacent to the distal end of the catheter.

Phelps teaches a catheter (10) with a collar (46) disposed adjacent its distal most end.

Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the medical device of Yoon with the collar as taught by Phelps.

Doing so would provide an attending physician with a means for determining the location of the catheter by magnetic or electromagnetic means (Phelps column 4, lines 30-35).

5. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon in view of Desai (US 5,857,464).

Yoon discloses all the limitations of claim 46, as discussed above in 3, but discloses four flaps (28) or two flaps (128) instead of a tricuspid flap configuration.

Desai teaches a catheter having a distal end valve (40) with three flaps (42).

Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the valve of Yoon with three flaps instead of two or four flaps, as

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there is no criticality to the number of flaps used in the end valve of Yoon, and Desai teaches that a tricuspid valve arrangement would perform equally well. It would be a simple matter of choosing a design for an end valve from existing designs known in the art, when each design would perform equally well. This skill is well within the capability of one of ordinary skill in the art.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wiktor (US 4,681,110), Jackson (US 4,850,969) and Yoon (US 5,752,970).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick M Buechner whose telephone number is (703) 308-2602. The examiner can normally be reached on 7:00am-4:30pm M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene Mancene can be reached on (703) 308-2696. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PB


Gene Mancene
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